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Biosimilar regulations in the ASEAN

Shivraj Dasari
SLS Cell Cure Technologies Pvt. Ltd., India

In the light of the expiration of a number of patents on first generation recombinant protein therapeutics, biosimilars have attracted a great deal of attention. However, as considerable differences exist between small molecule generics and biosimilars, there are uncertainties regarding the potential for the commercial success of biosimilars. With greater barriers to entry, biosimilars have attracted few entrants. Furthermore, because they have not been on the market for very long, the level of key stakeholder acceptance of biosimilar is still unknown. In the past, the "product is the process" paradigm dominated the opinions of the pharmaceutical and biotechnology industry as well as those of the regulators. However, with more and more originator companies having to change their processes - as a result of technological advances, changes in regulatory requirements or for economic reasons - this view is slowly changing. Furthermore, advances in physicochemical techniques used to characterize proteins have enabled the more thorough characterization of biologics derived from different processes. Consequently, regulatory bodies have recognized that it is now possible to approve biosimilars on the basis of abbreviated rather than full dossiers, relying on the results obtained in clinical trials with the reference product. However, as even the most advanced techniques can never fully characterize a protein, and a level of uncertainty remains, the European Medicines Evaluation Agency (EMEA) has taken the stance that some clinical trials are still required, and has issued guidance on the data necessary for approval. These requirements for clinical trial data are expected to evolve along with advances in analytical techniques and clinical experiences with the first biosimilars. The development of biosimilars requires significantly more resources than the development of small molecule generics. The complexity of the molecules and the lack of knowledge and techniques used in the analysis of biologics have resulted in stringent and extensive regulatory approval criteria. The amount of testing (including quality, pre-clinical and clinical testing) far exceeds the requirements for the regulatory approval of small molecule generics, and biosimilars are harder to produce. The regulatory requirements of ASEAN, EU and USFDA will be discussed to bring out the differences, and similarities, and finally the CTD requirements for ASEAN will also be discussed in detail.

Biography

Shivraj Dasari has a PhD in Microbiology, from Osmania University, Hyderabad, India. He has established his own company, SLS Cell Cure Technologies Private Limited, in India. His company is unique in having two cutting edge technologies, Molecular Diagnostics and Cell therapies. His Molecular Diagnostics business vertical offers Predictive Diagnostics, testing which helps in preserving wellness in addition to the regular Molecular diagnostics testing. The second business vertical, offers cell therapies including stem cell therapies to Diseases which have limitations in the standard Medical Practice. Earlier, he had worked for about 8 years with the Govt. of Malaysia in establishing the Biosimilar facilities and was also a member in the Technical committee which had formulated the Biosimilar guidelines for the ASEAN, along with the Clinical Trial requirements for ASEAN.

shivraj23@yahoo.com